



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2018-N-4162]**

#### **The Tobacco Products Scientific Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

**DATES:** The meeting will be held on February 6, 2019, from 8:30 a.m. to 5 p.m. and on February 7, 2019 from 8 a.m. to 1 p.m.

**ADDRESSES:** FDA White Oak Conference Center, Bldg. 31, Rm. 1503 (the Great Room), 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:** Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the *Federal Register* about last minute

modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* On February 6-7, 2019, the Committee will convene for two sessions. The first session will convene on February 6, 2019, during which the Committee will discuss an amendment to the modified risk tobacco product applications (MRTPAs), submitted by Swedish Match North America for the following snus smokeless tobacco products:

- MR0000020: General Loose;
- MR0000021: General Dry Mint Portion Original Mini;
- MR0000022: General Portion Original Large;
- MR0000024: General Classic Blend Portion White Large-12ct;
- MR0000025: General Mint Portion White Large;
- MR0000027: General Nordic Mint Portion White Large-12ct;
- MR0000028: General Portion White Large; and
- MR0000029: General Wintergreen Portion White Large.

The second session will convene, after the first session has concluded, on February 6, 2019, and continue on February 7, 2019. During the second session the Committee will discuss the MRTPA, submitted by Altria Client Services LLC on behalf of U.S. Smokeless Tobacco Company LLC for the following smokeless tobacco product:

- MR0000108: Copenhagen Snuff Fine Cut.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before January 22, 2019. Oral presentations from the public for the first session will be scheduled between approximately 10 a.m. and 10:30 a.m. on February 6, 2019, and for the second session between approximately 8 a.m. and 8:30 a.m. on February 7, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement describing the general nature of the evidence or arguments they wish to present, the names and email addresses of proposed participants, and the session during which they would like to speak, on or before January 14, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 15, 2019.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Caryn Cohen (see: FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 4, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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